In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-1463V

LISA NEUSS-GUILLEN,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Filed: June 12, 2024

Reissued for Public Availability: July 17, 2024

Lisa Neuss-Guillen, pro se, Indian Wells, CA, petitioner.
Voris Edward Johnson, U.S. Department of Justice, Washington, DC, for respondent.

Decision[1]

On September 24, 2018, petitioner, Lisa Neuss-Guillen, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012)[2], alleging that she suffered reactive polyarthritis following the receipt of a tetanus, diphtheria, and pertussis ("Tdap") vaccination in her left deltoid on October 22, 2015. (ECF Nos. 1, 23.) For the reasons discussed below, I conclude that petitioner is *not* entitled to an award of compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury.

[1] Pursuant to Vaccine Rule 18(b), this Decision was initially filed on June 12, 2024, and the parties were afforded 14 days to propose redaction. The parties did not propose any redactions. Accordingly, this Decision is reissued in its original form for posting on the court's website.

[2] Hereinafter all "§" citations within this decision are to portions of the Vaccine Act at 42 U.S.C. §300aa-10-34.

In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B). In this case, petitioner's alleged injury (reactive polyarthritis) is not an injury appearing on the Vaccine Injury Table.[3]

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). To so demonstrate, a petitioner must show that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In particular, a petitioner must show by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury in order to prove causation-in-fact. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For both Table and Non-Table claims, Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence . . . ." *Moberly*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen,* 418 F.3d at 1278; § 300aa-13(a)(1)(B).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3. Special masters must ensure each party has had a "full and fair opportunity" to develop the record but are empowered to determine the format for taking evidence based on the circumstances of each case, including having the discretion to decide cases without an evidentiary hearing. Vaccine Rules 3(b)(2) and 8(a) and (d). Special

[3] "Chronic arthritis" is a Table Injury, but only for vaccines containing rubella virus. 42 C.F.R. 100.3(a)

masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). If a party wishes to obtain review of a special master's decision, they must file a motion for review with the clerk of court within 30 days of the date the decision is filed. Vaccine Rule 23(a). No motions for extension of time are permitted with respect to motions for review. Vaccine Rule 23(b). A motion for review must be accompanied by a memorandum of numbered objections to the decision. Vaccine Rule 24.

II. Procedural History

At the time this case was filed, petitioner was represented by counsel.[4] This case was initially assigned to another special master who ordered petitioner to file complete medical records and a statement of completion. (ECF No. 4.) Petitioner's counsel filed petitioner's medical records on October 29 and October 30, 2018, and a statement of completion on November 6, 2018. (ECF Nos. 6-8.) However, respondent filed a status report on February 12, 2019, explaining that petitioner's Exhibit 4 consisted of 40,938 pages of "disorganized" and "confusing" medical records from USC's Keck Medicine, and identifying some addition records needed to complete his review. (ECF No. 9.)

The special master issued a scheduling order on March 4, 2019, directing petitioner to file a motion to strike Exhibit 4 and refile the records from Keck Medicine organized by date and with PDF bookmarks. (ECF No. 10.) Petitioner's counsel filed additional medical records on March 18, 2019. (ECF No. 11.) On April 8, 2019, the special master held a status conference to discuss how petitioner should proceed in order to address the issues raised regarding Exhibit 4. (ECF No. 12.) The special master concluded that the most effective way to proceed would be for petitioner to abandon her motion to strike, and instead, file an additional exhibit with the same records, categorized by type of record. (*Id.*) Petitioner filed additional records on April 15, 2019, and the reorganized records on July 3, 2019. (ECF Nos. 13, 18.)

On August 26, 2019, this case was reassigned to my docket. (ECF No. 20.) I held a status conference on September 4, 2019, to discuss the next steps in the case. (ECF No. 22.) During the status conference, respondent explained that there appeared to be very little in the record, specifically in Exhibit 4, supporting petitioner's claim of a vaccine injury. Petitioner's counsel advised that petitioner intended to file an amended petition with citations to the records supporting her allegations. Petitioner's counsel also expressed that petitioner was willing to file a statement from her treating rheumatologist, Dr. Ehresmann, in order to resolve the parties' concerns regarding the records from Keck Medicine. (*Id.* at 1.) Petitioner's counsel filed an amended petition on October 4, 2019, and a letter from Dr. Ehresmann on July 16, 2020. (ECF Nos. 23, 34; Ex. 8.) In

[4] Petitioner's counsel was terminated as counsel of record on August 11, 2022. (ECF No. 58.) Petitioner has indicated in multiple informal communications to the court that she does not trust the work that her counsel did in this case. However, petitioner has also had nearly two years to prosecute this case as a *pro se* litigant.

his July 2020 letter, Dr. Ehresmann opined that petitioner had suffered reactive arthritis post-vaccination. (Ex. 8, p. 4.)

On July 30, 2020, I held a status conference to follow up with the parties in regard to Dr. Ehresmann's letter at Exhibit 8. (ECF No. 35.) Respondent noted that there were several statements made by Dr. Ehresmann that were not corroborated by any of petitioner's medical records. Petitioner's counsel agreed, but explained that Dr. Ehresmann's letter was based on observations he made during petitioner's IVIG infusions. Respondent requested that petitioner provide citations to any records that support the contentions made in Dr. Ehresmann's letter. Due to the difficulty in assessing the weight to be given to Dr. Ehresmann's letter, and because this letter was the primary evidence supporting petitioner's alleged diagnosis, I recommended that the case proceed to a finding of fact in order to clarify the questions of diagnosis and onset. The parties agreed. (*Id.*)

Subsequently, the parties raised a concern to chambers that the process of converting Exhibit 4 to optical character recognition ("OCR") may have removed images from the medical records. Accordingly, on September 21, 2020, petitioner's counsel re-filed the Keck medical records previously submitted as Exhibit 4 without OCR capability as Exhibit 9. Petitioner's counsel filed a motion for a finding of fact on the existing record on September 30, 2020. (ECF No. 37.) Respondent filed his response on March 1, 2021, and petitioner's counsel filed petitioner's reply on April 12, 2021. (ECF Nos. 40, 41.)

On September 29, 2021, I issued a finding of fact. (ECF No. 42; *see also* 2021 WL 5764231 (Fed. Cl. Spec. Mstr. Sept. 29, 2021).) I concluded that "although I find that petitioner contemporaneously reported a subjective complaint of increased joint pain in her upper extremities sometime between mid-November 2015 and February 3, 2016, the remainder of her alleged symptoms are not preponderantly established as occurring within this period. On the current record, I am unable to conclude whether petitioner's post-vaccination symptom of increased upper extremity pain can be diagnosed as reactive polyarthritis." (ECF No. 42, pp. 1-2.) I indicated that additional expert evidence would be necessary and allowed petitioner an opportunity to indicate how she proposed to proceed. (*Id.* at 26.)

Petitioner's counsel filed several status reports advising that petitioner was consulting with a rheumatologist and determining how she would proceed. (ECF Nos. 43, 45, 46.) Subsequently, petitioner's counsel filed a motion to withdraw, which was granted on August 11, 2022. (ECF Nos. 48, 58.) After counsel withdrew and petitioner was designated as a *pro se* petitioner, I allowed petitioner further time to respond to the finding of fact. Specifically, I issued an order providing petitioner with additional copies of both the finding of fact and the decision awarding her departing counsel's attorneys' fees and costs, and allowing petitioner three months to either file an expert report supporting her claim or a brief pursuant to Vaccine Rule 8(d) explaining why she believes she is entitled to compensation based on the existing record. (ECF No. 59.)

Petitioner did not file any response to that order. On November 30, 2022, I issued a further order. Noting that petitioner had not responded to my prior order, I advised that I intended to issue a decision resolving the case on the existing record on January 30, 2023, unless petitioner took further action prior to that date. (ECF No. 64.) In response to that order, petitioner began sending e-mails to my chambers e-mail account beginning on December 24, 2022. These e-mails have been numerous and have been docketed as Court Exhibits I-XXIII. (ECF Nos. 65, 67-71, 73-81, 86, 90, 95, 98, 101, 103.) I repeatedly advised that the orders docketing these e-mails are for purposes of memorializing petitioner's *ex parte* communications. I have explained that these e-mails do not constitute filings in the case.[5] (ECF Nos. 68-69, 78, 95, 101, 103.)

Eventually, on September 27, 2023, petitioner filed a further opinion letter from Dr. Ehresmann dated September 12, 2023.[6] (ECF No. 85.) In his letter, Dr. Ehresmann disclaimed his prior reactive arthritis assertion, noting it "is probably not the best descriptor of her condition," but maintained his view that petitioner suffered some form of vaccine injury and recommended she be seen by a neurologist. (*Id.* at 2-3.) Dr. Ehresmann's letter was also accompanied by updated medical records. (*Id.*)

Following the submission of Dr. Ehresmann's letter, I directed respondent to file his Rule 4 Report, which he did on December 13, 2023. (ECF No. 92.) Respondent argued that petitioner had failed to establish that she suffered any defined or recognized injury and that, even assuming she had suffered reactive polyarthritis, she has not offered a reputable scientific or medical theory to support vaccine causation. (*Id.* at 12-

[5] These e-mails are long, far ranging in their subject matter, and can be difficult to follow. A close reading of the e-mails would reveal inconsistencies, assertions contrary to petitioner's claim, and misstatements of the history of this action. However, these e-mails are neither sworn statements nor filings by the petitioner. Accordingly, I have not considered them as evidence in this case. If I did consider them as evidence, they would be more likely to negatively affect petitioner's claim than support it. Therefore, even if I did consider them, it would not change the outcome. I have also considered whether the e-mails could be considered as argumentation pursuant to Vaccine Rule 8(d), but have not identified any line of reasoning within the e-mails that could reasonably support petitioner's claim. In particular, while petitioner expresses disagreement with my prior Finding of Fact, her e-mails do not include any argument that would support reconsideration of that ruling. I also note that these e-mails discuss injuries beyond what was included in the petition; however, petitioner has not substantiated those assertions and the e-mails also discuss other possible sources of injury apart from petitioner's vaccination. To the extent the e-mails are interpreted as seeking to change or expand the scope of the petition's allegations, petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). This decision is based upon a holistic review of the record evidence, including petitioner's medical records, her affidavit, and the opinion letters of her treating physician, Dr. Ehresmann. As discussed in the analysis below, I have examined whether petitioner has proven any vaccine-caused injury of any kind.

[6] I note that this letter was initially sent directly to my chambers e-mail account on September 12, 2023 by Dr. Ehresmann. However, I issued an order on September 15, 2023, advising petitioner that "Dr. Ehresmann's e-mail and accompanying letter have not been accepted as a filing in petitioner's case and will not be considered a part of the record of this case unless filed by petitioner herself using the proper filing procedures as outlined in prior orders." (ECF No. 84.) Petitioner did subsequently file the letter using appropriate procedures, confirming her intent to rely on the letter as evidence, and the letter was accepted into evidence despite having ultimately been filed out of time. (ECF No. 87.)

13.) Respondent requested that the case be dismissed. (*Id.* at 14.) In a separate status report, respondent proposed that an order to show cause be issued requiring petitioner to demonstrate why this case should not be dismissed. (ECF No. 93.)

On December 19, 2023, I issued an Order to Show Cause. (ECF No. 94.) In the order, I explained that this case had been the subject of years of litigation and that the order to show cause represented an opportunity to respond to respondent's report. (*Id.* at 1.) I provided a detailed explanation of the procedural history of the case, both while prosecuted by counsel and later by petitioner as a *pro se*, and explained petitioner's burden of proof. (*Id.* at 1-6.) I concluded that "[t]his case cannot be allowed to remain pending indefinitely and petitioner's filings to date strongly suggest that she will ultimately be unable to muster substantial additional medical support for her claim. Accordingly, I conclude that this Order to Show Cause is appropriate to give petitioner *one final* opportunity to develop her claim." (*Id.* at 7 (emphasis in original).) I allowed petitioner 90 days, until March 15, 2024, to file whatever additional evidence she wished to present along with a written brief pursuant to Vaccine Rule 8(d) setting forth her arguments as to why she believes she should be found entitled to compensation. (*Id.*) I advised that I would thereafter resolve the case on the record as it stands at that time.

On March 13, 2024, petitioner filed a motion for extension of time. (ECF No. 97.) Petitioner represented that she had an upcoming neurology appointment on April 15, 2024, that could not be scheduled prior to the deadline set by the Order to Show Cause. (ECF No. 102.) Noting that Dr. Ehresman's letter had recommended a neurology evaluation, and accepting petitioner's assertion that the appointment could not have been scheduled earlier, I granted petitioner's motion and extended her show cause deadline to May 13, 2024. (*Id.*) However, I explained that "the relief granted by this Order is limited to permitting petitioner an opportunity to file records associated with her April 15, 2024 neurologist appointment." (*Id.* at 2.) I further explained that "[o]nly if the records of the April 15, 2024 appointment present substantial new evidence supporting an identifiable vaccine-related injury will I entertain any request for further proceedings. Otherwise, I still intend to resolve this case based on the existing record as it exists following petitioner's May 13, 2024 deadline." (*Id.* (emphasis omitted).)

In an e-mail to chambers of April 16, 2024, petitioner suggested she had rescheduled her neurology appointment. (Court Ex. XXIII.) However, she did not provide any explanation for the rescheduling or suggest she intended to seek additional time to respond to the prior order to show cause. (*Id.*) Petitioner was advised that the e-mail is not a filing in the case and that "[i]f petitioner wishes to introduce evidence into the record or request relief from any pending deadline, she must follow the procedures for completing a formal filing with the court." (ECF No. 103.) Petitioner never filed any motion for extension of time or any response to the Order to Show Cause. However, I did interpret one statement within petitioner's e-mail as potentially requesting a status conference. I issued a follow up order, noting that the record of the case closed after her show cause deadline had passed, but giving petitioner an opportunity to confirm whether she would like to request that a status conference be held prior to issuance of

any decision so that she could raise any arguments or ask any questions that she may have. (ECF No. 104.) Petitioner did not respond to that order.

In light of the above, I conclude that this case is now ripe for resolution based on the current record. Petitioner has had a full and fair opportunity to develop the record of this case.[7] *See* Vaccine Rule 3(d); Vaccine Rule 8(d).

III. Factual History

a. Petitioner's medical records through 2018 as originally filed by prior counsel

Prior to her vaccination, petitioner had a long history of Behçet's disease.[8] (Ex. 3, pp. 4-7; Ex. 9, pp. 1668-69, 13789-92.) Her medical history also included joint pain (suspected to be inflammatory), obesity, gastric bypass surgery, osteoarthritis, a methicillin-resistant Staphylococcus aureus (MRSA) infection, pelvic pain, goiter, and ganglion. (Ex. 9, pp. 13789-92, 15113-15, 21747, 21749-55, 24111, 24546-47, 24555-56.) Petitioner's joint pain was affecting her ability to ambulate as early as 2008. (*Id*. at 1669.) Petitioner's records specifically note that she experienced chronic pain with neuropathic and mechanical features, and complained of joint, hip, ankle, and back pain that limited her ability to walk. (*Id.* at 1668-69, 13789-92, 24546-47.) To manage her symptoms, petitioner was undergoing monthly IVIG infusions, and prescribed methadone, Vicodin, oxycodone, morphine, Norco, and Percocet. (*Id.* at 1668, 13789-92, 15113-14, 24548-50.) Petitioner's medical records reflect that her Behçet's disease was reasonably controlled, but that she was experiencing chronic pain. (Ex. 3, p. 13; Ex. 9, pp. 21749-52.)

Petitioner reported to Beaumont Urgent Care Center for a finger laceration on October 22, 2015. (Ex. 3, pp. 4-7.) She received several stitches and a Tdap vaccination. (*Id.*) The next document available in the medical record following

[7] The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. § 300aa-12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Human Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). Special masters are simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 401-03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns ex rel. Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

[8] Behçet's disease or syndrome is "a variant of neutrophilic dermatosis of unknown etiology, involving the small blood vessels, characterized by recurrent aphthous ulceration of oral and pharyngeal mucous membranes and genitalia, with skin lesions, severe uveitis, retinal vasculitis, optic atrophy, and often involvement of the joints, gastrointestinal system, and central nervous system." *Behçet's Syndrome*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (33d ed. 2020).

petitioner's vaccination is a letter to Gallant Medical Supply from Dr. Ehresmann, dated February 3, 2016. The purpose of the letter was to support petitioner's request for a motorized scooter or wheelchair. The letter describes petitioner's condition as:

> Behcet's syndrome, which results in systemic illness with joint pain diffusely in addition to . . . significant osteoarthritis of the lower extremities, particularly the left knee . . . and in the right lower extremity she has a ganglion cyst which is causing severe pain with weightbearing on that extremity. Additionally, she has upper extremity symptoms with epicondylitis and joint pain, much of which exacerbated following a tetanus immunization a few months ago which resulted in a reactive polyarthritis.

(Ex. 9, pp. 27199-201.) Dr. Ehresmann also discussed increasing hip pain attributable to a traumatic fall occurring two years prior. (*Id*.)

On March 7, 2016, petitioner received a bilateral hip x-ray. (Ex. 9, p. 26262.) The x-ray revealed mild degenerative changes of the bilateral hips, pubic symphysis, and visualized lumbosacral spine. There was mild generalized osteopenia, but no acute fracture. (*Id.*) Petitioner also reported a headache, leg pain when walking, joint stiffness, tingling, generalized muscle aches and pains, and lower back pain. (*Id.* at 26699.) She did not report any shoulder or neck pain.

On April 12, 2016, Dr. Ehresmann referred petitioner to cardiologist Dr. Ray Matthews after an abnormal ECG. (Ex. 9, pp. 27197-98.) In his referral letter, Dr. Ehresmann wrote that petitioner was a:

> 57-year-old woman with a long history of Behcet syndrome, with many cutaneous and mucosal ulcerative lesions superimposed on other problems which include prior obesity and gastric bypass with associated problems . . . . . .
>
> . . . . .
>
> . . . She has been intermittently on steroids in the past but none recently, and receives periodic IVIG therapy and rituximab to control the mucocutaneous manifestations of her disease.
>
> Chronic pain is a significant issue, with the patient requiring substantial amounts of opioid on a regular basis, which she is trying to gradually taper.

(*Id.*) Dr. Ehresmann did not mention reactive arthritis in this letter.

Petitioner was seen for a cardiology evaluation by Dr. Matthews on April 13, 2016. (Ex. 9, pp. 31106-08.) Dr. Matthews noted that petitioner was "a challenging history teller and speaks with rapid pressured speech and expands off into tangents."

(*Id.* at 31106.) He discerned that petitioner had some chest discomfort, which she believed was congestive heart failure. (*Id.*) Petitioner had an abnormal ECG, which was consistent with hibernating myocardium. Dr. Matthews listed petitioner's Behçet's, gastric bypass, skin lesions, and other symptoms in petitioner's medical history, but did not include reactive arthritis. (*Id.* at 31106-08.)

Dr. Ehresmann wrote another letter on May 3, 2016, this time addressed to an attorney and regarding a dispute with petitioner's credit union. (Ex. 9, pp. 27610-11.) The letter explains petitioner's medical history and requests that it be considered a "major medical hardship." (*Id.* at 27610.) Dr. Ehresmann mentioned petitioner's "severe systemic illness" associated with Behçet's syndrome; a "traumatic injury," which "further compromised" her functional capacity; and a possible "significant cardiac issue, for which she needs some additional medical and radiographic evaluations." (*Id.* at 27610-11.) Dr. Ehresmann did not mention reactive arthritis. (*Id.*)

Petitioner received an IVIG infusion at Keck Hospital on July 6, 2016. (Ex. 9, 30243.) Prior to her infusion, petitioner reported to Dr. Ehresmann for a follow up on her right ankle ganglion cyst pain. (*Id.* at 30690.) Dr. Ehresmann listed a variety of problems in petitioner's chart including Behçet's, goiter, osteoarthritis, anemia, and hypothyroidism. (*Id.* at 30691.) Although he also listed "other specified disorders of ankle and foot joint," he did not specifically mention reactive arthritis. (*Id.*)

On November 13, 2016, Dr. Ehresmann wrote another letter on petitioner's behalf, this time to Banning Superior Court, requesting that petitioner be provided additional time in a court proceeding that appears to have been related to the dispute with her credit union and a foreclosure on her home. (Ex. 9, pp. 29748-50.) Dr. Ehresmann explained that petitioner's "systemic medical illness" was associated "with many painful ulcerative skin lesions, as well as systemic complications and the need for complex medical treatments and medications." (*Id.* at 29748.) Dr. Ehresmann did not mention reactive arthritis in this letter. (*Id.* at 29748-50.)

Petitioner once again saw Dr. Ehresmann for a follow up on her Behçet's on December 6, 2016. (Ex. 9, pp. 29311-14.) Dr. Ehresmann noted petitioner's gastric bypass, chronic absorption difficulties, lumbar disc disease, foot/ankle ganglion, hypertension, hypothyroidism, goiter, microcytic anemia, osteoarthritis involving her knees, and post-contusion pain in her hips. (*Id.* at 29311-12.) Petitioner's physical exam revealed patellofemoral bilateral knee pain, trochanteric tenderness, and bilateral guarding of hip range of motion, with no signs of proliferative synovitis. (*Id.* at 29313.) Dr. Ehresmann's impression included Behçet's, gastric bypass, iron deficiency, hypertension, coronary artery disease, hypothyroidism, goiter, osteoarthritis, hip trauma, and panic symptoms, but did not mention reactive arthritis. (*Id.* at 29314.)

Dr. Ehresmann wrote another letter for petitioner on January 18, 2017, this time addressed to petitioner's insurance reviewer for pharmacy benefits. (Ex. 9, pp. 29348-49.) In his letter, Dr. Ehresmann explained that petitioner's Behçet's syndrome had caused "painful deep ulcers in various body areas that have been refractory to many

therapies but somewhat improved with IVIG and B-cell depletion with rituximab." (*Id.* at 29348.) Dr. Ehresmann also noted that petitioner had "significant back disease and osteoarthritis of the knees and hip symptoms post-contusions." (*Id.* at 29348-49.) Dr. Ehresmann again did not mention reactive arthritis.

On February 28, 2017, petitioner received an IVIG infusion and a steroid injection in her left knee at Keck Medicine. (Ex. 9, p. 29065.) Petitioner reported that she felt very tired and complained about the hospital food but did not mention anything about arthritic pain. (*Id.*) She also received x-rays of her left shoulder, pelvis, and both elbows, knees, and ankles. (*Id.* at 28670-77.) Her shoulder x-ray revealed mild bilateral acromioclavicular osteoarthrosis and diffuse osteopenia. (*Id.* at 28670.) Her elbow x-ray showed osteopenia and mild ulnotrochlear osteoarthrosis with small osteophyte. (*Id.* at 28673.) Her pelvic x-ray showed no acute osseous abnormality, mild bilateral hip osteoarthrosis, mild degenerative changes of the pubic symphysis, and diffuse osteopenia. (*Id.* at 28674.) Her ankle x-ray showed moderate to severe right talonavicular arthrosis, mild arthrosis involving left talonavicular and bilateral calcaneocuboid joints with a possible inflammatory etiology, small bilateral tibiotalar joint effusions, and diffuse osteopenia. (*Id.* at 28675.) Her knee x-ray showed symmetric mild bilateral medial and lateral tibiofemoral compartment joint space narrowing, mild bilateral patella, small bilateral knee joint effusions, and diffuse osteopenia. (*Id.* at 28677.)

Dr. Ehresmann wrote another letter on May 2, 2017, addressed to a judge of the Pomona County Superior Court in Los Angeles, California, seeking to delay petitioner's case six to eight months on account of her medical condition. (Ex. 9, pp. 33356-57.) The nature of the case at issue is not indicated.

Petitioner received another IVIG infusion at Keck Medicine on July 17, 2017. (Ex. 9, pp. 32729-33.) She reported open lesions on her abdomen and legs, and increasing pain in her left knee and both ankles where she had radiographic osteoarthritic changes. (*Id.* at 32729.) Petitioner's problem list at this visit included anemia, Behçet's, goiter, edema, ganglion, gastric bypass, hypertensive disorder, hypothyroidism, osteoarthritis, vitamin B deficiency, and other specified disorders of ankle and foot joint. (*Id.*) Although none of petitioner's records of this visit mention reactive arthritis, the multidisciplinary forms do state that petitioner "had a severe adverse reaction with tetanus vaccine in the past." (*Id.* at 33039.) Petitioner was discharged from her inpatient IVIG infusion on July 18, 2017. (*Id.* at 32687.) On discharge, petitioner noted that she was concerned that her Tdap vaccination "precipitated growths in her joints and tendons that are worsening." (*Id.*)

Petitioner received steroid injections in both ankles and her left knee, as well as a ganglion cyst aspiration, on August 9, 2017. (Ex. 9, pp. 33024-25.)

Petitioner returned to Keck Medicine on September 7, 2017, for an inpatient IVIG infusion. (Ex. 9, p. 32025.) During this visit, petitioner noted that "since her last IVIG infusion, her diffuse arthralgia symptoms worsened over the last 4 weeks and she

started developing a bitemporal frontal headache that was chronic and worsening progressively over the last couple of days." (*Id.*) She described her headache as "dull . . . with some sharp spikes in intensity and the sensation of some neck tightness." (*Id.*) Petitioner also reported diffuse pain in her joints, most notably the bilateral DIP and PIP joints of both hands. (*Id.*)

Petitioner was also seen by her primary care physician Dr. Donna Shoupe for a routine check-up on September 7, 2017. (Ex. 9, p. 35219.) Petitioner's history of present illness included Behçet's, gastric bypass, arthritis, and notes that petitioner "feels [that she] reacted to [the] tetanus vaccine;" however Dr. Shoupe did not opine on petitioner's alleged vaccine reaction in this record. (*Id.*) Petitioner's problem list at this visit included anemia, Behçet's, goiter, edema, abnormal gynecological exam, flexor tenosynovitis of finger, ganglion of tendon sheath, history of gastric bypass, hypertensive disorder, hypothyroidism, osteoarthritis, osteoporosis, other specified disorders of ankle and foot joint, vaginal atrophy, and vitamin B deficiency. (*Id.*) Reactive arthritis was not included in this record.

Petitioner was next seen by Dr. Ehresmann on October 11, 2017 for redness and edema in her left leg. (Ex. 9, p. 34360.) Petitioner reported that she had multiple episodes of stabbing abdominal pain, complained of increased urinary urgency, mild eye burning, and discomfort in the left side of her throat. (*Id.*) Petitioner did not report any arthritic issues, nor were any arthritic issues observed on examination. (*Id.* at 34360-61.)

Petitioner received another IVIG infusion at Keck Medicine on October 12, 2017. (Ex. 9, p. 34315.) Petitioner "stated that she had worsened headache, neck tightness, and pain at her DIP and PIP joints since her last [IVIG infusion]. Her headache is dull and intermittent. She did not have associated nausea, vomiting, vision changes, lightheadedness, and fever/chills." (*Id.*)

On November 22, 2017, Dr. Ehresmann wrote another letter to Pomona County Superior Court, describing petitioner's condition and requesting that her court date be continued. (Ex. 9, p. 34393-94.) Dr. Ehresmann noted that petitioner's symptoms included open lesions, kidney function abnormalities, anemia, weakness, osteoarthritis, and cardiac compromise. (*Id.*) He did not mention reactive arthritis. (*Id.*)

Petitioner was seen again by Dr. Ehresmann on January 9, 2018, for a follow up on her osteoarthritis and emerging throat issues. (Ex. 9, p. 35780.) She complained of a lesion in her throat, skin lesions, eye pain, foot pain, abdominal pain, a thyroid nodule, and left sided throat pain. (*Id.*) Petitioner's exam revealed no inflammatory arthritis, some guarding bilateral crepitation in the hips and knees, no instability, left foot ganglion, no edema, no clubbing, no synovitis, bilateral ephemeral arthritis, no effusion, no ankle synovitis, and decreased size in petitioner's ganglion. (*Id.* at 35781.) Dr. Ehresmann's assessment included flexor tenosynovitis, cervical radiculopathy, diffuse goiter, ganglion of the tendon sheath, osteoarthritis, osteoporosis, splenic lesion,

thoracic arthritis, and thyroid nodule. (*Id.* at 35781-83.) He did not mention reactive arthritis in this record. (*Id.*)

Petitioner returned to Dr. Ehresmann on February 20, 2018 for a follow up on her osteoarthritis and Behçet's. (Ex. 9, p. 39355.) During this visit petitioner complained of open sores, neck pain, and a lesion in her ear. Petitioner's assessment remained unchanged, and Dr. Ehresmann again did not include reactive arthritis in his diagnosis. (*Id.* at 39355-58.)

On February 21, 2018, petitioner was seen by Dr. Loni Tang at Keck Medicine. (Ex. 9, p. 39349.) Petitioner was in Los Angeles and requested an IVIG infusion out of convenience since she typically commuted from Palm Springs. She reported having some tendonitis related to her earlier tetanus shot, but her EMG was negative. Her ongoing problem list was largely unchanged from her previous records, with the addition of hoarseness and splenic mass. Dr. Tang's record does not reflect any observation of arthritis or memorialize any complaints from petitioner regarding arthritis. (*Id.* at 39349-52.)

On March 20, 2018, petitioner was seen by Dr. Ehresmann for radiculopathy, osteoporosis, and osteoarthritis. (Ex. 9, p. 38708.) Petitioner reported pain in her right lateral side, cervical spine, and "crunching" in her left elbow and wrist. (*Id.*) She requested a B12 injection and a letter to Pomona County Superior Court regarding her inability to represent herself in court. She also requested a letter to the California Department of Health Services recommending she be temporarily excluded from medical managed care plans. (*Id.* at 38708-09.) Her exam revealed bilateral tenderness in her AC and glenohumeral joints, some degenerative mid-foot osteoarthritis changes bilaterally, primary osteoarthritis in her hands, and patellofemoral crepitus in both knees. (*Id.*) There is no mention of reactive arthritis in this record.

Dr. Ehresmann wrote two letters on March 20, 2018, one to Pomona County Superior Court and one to the California Department of Health Care Services. (Ex. 9, pp. 38751-55.) In both letters, Dr. Ehresmann referenced petitioner's difficulty with treatment and discussed her complicated osteoporosis. (*Id.*) However, he did not mention reactive arthritis in his letter to the judge. He did, however, mention in his letter to the California Department of Health Care Services that petitioner "developed a severe set of symptoms following immunization for tetanus about 2 years ago and has had progressive joint pain and other complicating symptoms since that time." (*Id.* at 38754.)

On May 11, 2018, petitioner reached out to Dr. Ehresmann, reporting that she was experiencing left ear pain, mild pain in her jaw, inflammation in both hands, a noticeable change in her lesions, spinal cord pain, and "horrible" pain in her feet. (Ex. 9, p. 38225.) Petitioner reported that she felt all of these symptoms were the result of her Prolia medication and that she would not be able to take the Prolia without methadone. (*Id.*)

b. Petitioner's affidavit

Petitioner filed an affidavit, signed September 18, 2018, describing the course of her condition. (Ex. 1.) She stated that prior to vaccination, around the age of forty, she began feeling unwell. She was seen by Dr. Ehresmann who diagnosed her with Behçet's disease. Petitioner's symptoms "took [her] out of normal life," and the fatigue was so intense that petitioner struggled to lift a roll of toilet paper. (Ex. 1, p. 1.)

Petitioner explained that Behçet's is a multi-system disorder which made her IVIG dependent. This means that petitioner is hospitalized each month to receive IVIG infusions. During the first 15 years of her disease, petitioner would receive her infusions at Norris Cancer Day Hospital, but then switched to USC's Keck Hospital. (Ex. 1, p. 1.)

When petitioner began her IVIG therapy, it "helped intensely." (Ex. 1, p. 1.) She described her disease as a lifelong condition, which causes severe lesions in her mouth and all over her body. Petitioner explained that in 2009, she had over 200 open lesions on her body, and because the nerve endings are at skin level, the lesions were agonizing and "similar to being in a fire." She also experienced fevers, chills, and skin necrosis. (*Id.*) Petitioner explained that prior to her vaccination, she was using one type of pain medication for her condition and another for "in-between pain," but stated that she "was nearly completely off of them prior to vaccination." (*Id.* at 2.)

Petitioner stated that she cut her finger on October 22, 2015 and went to Beaver Medical Group where she received stitches and a tetanus vaccination. She reminded the physician about her autoimmune condition but was assured that she would be fine. Petitioner notes that, at this time, she was already told that she was not to receive the pneumonia vaccine. (Ex. 1, p. 2.)

A few weeks later, petitioner reported "feeling different." (Ex. 1, p. 2.) She stated that "maybe a week and a half after getting the stitches out of [her] finger, I started having headaches and felt pain in my left arm." (*Id.*) Although petitioner did not think much of this, she told her doctor who thought the pain was caused by petitioner's weaning off narcotics. Petitioner told her doctor that "[i]t felt like everything changed to a much higher level of pain from [her] toes to [her] brain." (*Id.*)

Petitioner described feeling painful spasms in her muscles that brought her to tears. She began treating her pain with narcotics, and stated that she began to consider whether these new sensations were related to her tetanus vaccination. She noted experiencing a stiff neck and right shoulder pain that switched to her left shoulder and left arm. She reported that "it felt like nerve pain with pain all over my body." Petitioner explained that this pain continued throughout 2016, and that in February of 2016 she began to experience a painful "bone crunching" sensation in her left and then her right elbow. (Ex. 1, p. 2.)

In May of 2016, petitioner felt that the bone crunching sensation affected her whole body. She noticed terrible pain in the joints of her fingers and toes in "the exact

same place on every finger and toe." She noticed that each of her knuckles were very painful and swollen, and that her mind was also affected, causing her to have difficulty organizing her thoughts. (Ex. 1, p. 2.)

Petitioner averred that she was diagnosed with reactive polyarthritis, and that Dr. Ehresmann associated this diagnosis to petitioner's tetanus vaccination. (Ex. 1, p. 2.)

c. Dr. Ehresmann's July 16, 2020 letter

On July 16, 2020, petitioner filed a letter dated July 14, 2020 from her treating rheumatologist, Dr. Glenn Ehresmann, addressed to petitioner's counsel, Mr. Downing. (Ex. 8.) Dr. Ehresmann begins his letter explaining that Behçet's is "a rare chronic multisystem inflammatory disease which has prominent mucosal and cutaneous ulcerative lesions as the major manifestation for [petitioner]." (*Id.* at 1-2.) According to Dr. Ehresmann, Behçet's may have various manifestations, including central nervous system involvement, ocular involvement, genital involvement, or other mucosal or cutaneous manifestations. (*Id.* at 2.)

Dr. Ehresmann explains that petitioner's treatment has included IV infusions of rituximab and antibodies to B cells, which seemed to be driving petitioner's disease. He explains that B-cell depletion has been "partially effective in controlling the number and intensity" of petitioner's lesions, but that petitioner's immunoglobulin level dropped, placing her at risk for complicating infections. (Ex. 8, p. 2.) Consequently, she has received monthly IVIG infusions, which have also had positive effects on her Behçet's disease. (*Id.*)

Dr. Ehresmann also indicates that petitioner has evidence of osteoarthritis characterized by mild changes in several of her joints evidenced on x-rays over the past ten years. Petitioner also has coronary artery disease, which was stable at the time he wrote his letter. Although a cardiologist recommended further evaluation of petitioner's coronary disease, Dr. Ehresmann reports that petitioner's illness precluded her from completing some of the recommended studies. Dr. Ehresmann notes that it is unsurprising that petitioner shows signs of osteoporosis due to her sedentary lifestyle and complications related to her vaccination. Petitioner also has a large goiter but no evidence of hyperthyroidism, which Dr. Ehresmann explains would lead to worsening osteoporosis. (Ex. 8, p. 2.)

Dr. Ehresmann further explains that prior to her immunization, petitioner's medical status was relatively stable with recurrent cutaneous ulcers requiring rituximab and IVIG, but nothing that required chronic corticosteroid therapy. (Ex. 8, p. 2.) After her vaccination, Dr. Ehresmann reports that petitioner developed pain in her shoulders and other areas that were not involved in her Behçet's symptoms. In the five years preceding his letter, he explains that her symptoms of joint pain "have been far out of proportion to any radiographic changes associated with what has been described in the report" as "mild osteoarthritis." (*Id.*)

Dr. Ehresmann states that petitioner has also experienced symptoms that suggest an enthesitis[9] involving her achilles and biceps tendons, as well as joint pain in her hands that "felt [like] her digits were breaking off," even though the changes exhibited on her x-rays taken as recently as May 2020 were described as "minimal osteoarthritis at the thumb carpometacarpal joints." (Ex. 8, p. 2.) Additionally, Dr. Ehresmann points out that petitioner complained of "exquisite pain in the hips bilaterally to the point of severe difficulty walking," in March of 2016, and her x-rays only showed "very mild joint space narrowing with minimal marginal osteophytes." (*Id.* at 2-3.) Dr. Ehresmann also notes a February 2017 radiology report, which "confirmed evidence of right talonavicular arthrosis with extension into adjacent areas, with enough synovitis noted on the MRI that an inflammatory etiology was suspected." (*Id.* at 3.) However, he notes that petitioner's inflammatory markers, including her sedimentation rate and CRP, were typically low or normal in her routine lab work. Dr. Ehresmann explains that petitioner's MRIs have shown tibiotalar joint effusions consistent with an inflammatory response and not simply degenerative changes. (*Id.*) Dr. Ehresmann believes that petitioner's joint symptoms "cannot be explained by her Behcet's, nor the minimal degenerative changes that are present radiographically." (*Id.*)

According to Dr. Ehresmann, petitioner also experienced neuropathic symptoms, which were evaluated by EMG/NCS studies that excluded any sort of entrapment neuropathy. Diabetic neuropathy was not considered because petitioner was not found to be diabetic. Dr. Ehresmann believes that there may, however, be a component of small fiber neuropathy that could not be confirmed on EMG/NCS. Because all of these symptoms evolved following petitioner's vaccination, Dr. Ehresmann believes that they are "certainly consistent with post-vaccination responses." (Ex. 8, p. 3.) Dr. Ehresmann explains that petitioner's esophageal dysfunction may be neuropathic in nature as well, given that no mechanical abnormality was ever discovered on evaluation. (*Id.*) He continues that petitioner's esophageal study did not suggest Behçet's or other tissue disease were to blame. (*Id.* at 3-4.)

Dr. Ehresmann concludes his letter by explaining that, although petitioner endured many difficult symptoms as a result of her Behçet's illness prior to her vaccination, her inflammatory joint pain and neuropathic symptoms only arose after she received her tetanus vaccination. Because no other process can explain the onset of these symptoms, Dr. Ehresmann concludes that petitioner's tetanus vaccination "resulted in a reactive arthropathy superimposed on any pre-existing degenerative change, which was very modest. The neuropathic symptoms are also attributed to the tetanus vaccination." (Ex. 8, p. 4.) Dr. Ehresmann acknowledges that "Behcet's disease can certainly have neurologic sequelae," but that "the absence of any nerve conduction or EMG abnormalities favors another etiology." (*Id.*)

a. Petitioner's 2023 medical record as later filed by petitioner *pro se*

[9] "Enthesitis" is "inflammation of the muscular or tendinous attachment to bone." *Enthesitis*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (33d ed. 2020).

Petitioner later filed additional medical records with Dr. Ehresmann's September 2023 letter. Specifically, Dr. Ehresmann's letter was accompanied by his records from encounters of April 14, 2023, May 3, 2023, June 6, 2023, June 23, 2023, July 11, 2023, and August 8, 2023. (ECF No. 85, pp. 5-33.) No records have been filed for the period from May 11, 2018 to April 3, 2023.

On April 14, 2023, petitioner had a follow up telehealth encounter with Dr. Ehresmann's office. (ECF No. 85, pp. 29-33.) In addition to discussion of her other chronic complaints, petitioner reported that she "still struggles with joint sx which are multifactorial with osteoarthritis of knees for several years which had initially been worse in the patellofemoral compartment." (*Id*. at 30.) It was further recorded that "[t]he sx seem to be much worse after vaccination in 2015 with complaints of pain in elbows, hands, feet that were more tenosynovitis than articular. She describes pain in L arm ulnar distribution that led to prior EMG nerve conduction studies which were negative several years ago. There was MRI evidence of tendonitis involving hamstring muscles 2 years ago and as far back as 2017 she also had radiographic changes of talonavicular joint which were interpreted as associated with post-inflammatory arthritis." (*Id*.) It is noted that petitioner's functional status has deteriorated significantly, but this was thought to be mostly due to her advanced osteoarthritis of the knees. (*Id*. at 31.) In addition to her other conditions, petitioner's assessment included "allergic to tetanus vaccine." An accompanying explanation indicates that she had "[s]x of tenosynovitis/reactive joint disease are difficult to separate from progressive degenerative disease. She understands this but also reminds me she did not have tenosynovitis sx before vaccination." (*Id*. at 32.)

The history of present illness for petitioner's May 3, 2023 encounter indicates that "[a]fter her tetanus vaccination in 2015, pt reports worsened bilateral arm pain, left worse than right, and flu-like symptoms." (ECF No. 85, p. 25.) Under review of systems, it is explained that "the situation of her osteoporosis is very complicated." After discussing a number of factors potentially affecting that condition, the record states that "[t]he degree the vaccination can contribute is difficult to assess but bone density has dropped considerably between 2011 and 2017, 2 years after the vaccination." (*Id*. at 26.) Again, the assessment lists "[a]llergic to tetanus vaccine" among petitioner's conditions. It explains:

> Patient continues to have symptoms attributed to post-tetanus. Enthesitis/arthritis is consistent with reactive process and some superimposed neuropathic pain which may be small fiber neuropathy. EMJ nerve negative for entrapment syndrome, and no evidence of neuropathy or radiculopathy to explain those persistent symptoms. I do not think [this] patient is a good candidate to confirm small fiber neuropathy. Patient on large doses of opioids. She requires large doses due to gastric bypass and poor absorption. Avoid NSAIDS as much as possible due to risk and impaired renal function impairment as well as her CAD.

(*Id*. at 27.) This record also includes a list of immunizations, indicating that several influenza and Covid-19 vaccinations were administered between 2013 and 2022 without any adverse event. (*Id*.)

As of June 6, 2023, petitioner's history of present illness recorded that "[s]he has continued to have neuropathic pain sx in LUE after tetanus vaccination several years ago. There has not been marked inflammatory response but neuropathic pain has been persistent, vexing, and limiting. She has had negative electrodiagnostic studies in the past." (ECF No. 85, p. 20.) Under assessment, petitioner's conditions continued to include "[a]llergic to tetanus vaccine." For this encounter, the accompanying notation indicates that she "[c]ontinues to have brachial neuropathic sx. Joint sx seem more degenerative than inflammatory especially in knees." (*Id*. at 22.)

As of June 23, 2023, petitioner's history indicated "[t]he pt continues to have episodes of neuropathic pain in LUE attributed to the prior tetanus vaccination. She is known to have cervical degenerative disease likely exacerbated by automobile accidents in 2020 and more recently." (ECF No. 85, pp. 15-16.) The assessment of "[a]llergic to tetanus vaccine" states only "[p]ersistent sx as discussed." (*Id*. at 17.)

As of July 11, 2023, petitioner presented for follow-up with complaints, including "post tetanus vaccination neuropathic/musculoskeletal symptoms." (ECF No. 85, p. 10.) It is further explained that

> Left upper extremity neuropathic symptoms are intermittently symptomatic and have been more or less consistently present since her vaccination symptoms began several years ago. Articular symptoms are difficult to evaluate because they are combination of degenerative and perhaps superimposed reactive, in addition to which she has had two car accidents with trauma to knees, neck, and back.

(*Id*.) The assessment for "[a]llergic to tetanus vaccine" indicates that she "continues with neuropathic and intermittent musculoskeletal symptoms consistent with enthesitis superimposed on her osteoarthritis." (*Id.* at 13.)

Finally, petitioner's August 8, 2023, assessment indicates, in pertinent part: "continues to have neuropathic musculoskeletal symptoms which began post tetanus immunization and persist particularly L UE but has had LE symptoms as well with MRI changes in post consistent with enthesitis." (ECF No. 85, pp. 5-8.)

d. Dr. Ehresmann's September 12, 2023 letter

In his September 12, 2023 letter, Dr. Ehresmann stresses that he has been petitioner's treating rheumatologist for over two decades and the principle physician managing her medical status during that time. (ECF No. 85, p. 1.) He explains that the letter is to provide an "update you on her status post vaccination reaction following her

2015 tetanus immunization. This is not a medical/legal report, but rather a review and update by the patient's treating physician." (*Id*.)

Dr. Ehresmann explains that several conditions are important to assessing petitioner's condition. First, he explains that petitioner's case is complicated by persistent hypogammaglobuinemia related to her rituximab and anti B cell therapy for her Behçet's syndrome. She receives periodic IV gammaglobulin replacement, which itself has further side effects (fevers, rashes, and headaches) for which she has intermittently taken steroids. (ECF No. 85, p. 1.) Second, he explains that petitioner has pre-existing osteoarthritis affecting her knees and spine. Third, petitioner suffers complications from a prior gastric bypass surgery that have required her to use increased doses of the narcotic pain medication that controls her pain symptoms. Fourth, she has a large goiter and has inadequate thyroid levels despite treatment. Fifth, she is profoundly vitamin D deficient. Sixth, her conditions, especially her arthritis of the knees, is further affected by obesity. (*Id*. at 1-2.)

After acknowledging these issues, Dr. Ehresmann additionally asserts that "her pain symptoms did change significantly following the 2015 tetanus vaccination. This patient reported neuropathic and musculoskeletal symptoms that were different than her pre-existing knee, neck, and back symptoms. The descriptions were quite dramatic and the reported pain symptoms more severe than anything she previously experienced, especially with respect to the left upper extremity." (ECF No. 85, p. 2.) Dr. Ehresmann acknowledged, however, that "[r]eactive arthritis is probably not the best descriptor of her condition as symptoms were more nerve tendon and soft tissue related." (*Id*.)

Dr. Ehresmann indicated that objective testing, including EMG, MRI, and x-ray imaging, did not reveal any alternative diagnosis for her symptoms, though he acknowledged that x-ray imaging did show petitioner's pre-existing osteoarthritis. One MRI of petitioner's ankle showed evidence of inflammatory changes to the ankle. (ECF No. 85, p. 2.)

Dr. Ehresmann writes:

> It has been my understanding that most patients with post tetanus vaccination symptoms will have brief symptoms that resolve without specific therapy. My care of this patient has been focused on treating her potentially life threatening Behcet's syndrome and associated complications. There is not much written about her post vaccination symptoms until they continued to persist well beyond [what] was more typically a self-limited course. I am aware that severe complications such as Guillain Barre syndrome have been reported following tetanus vaccination [that] generally occur relatively early after vaccination. Her pain symptoms did begin in the weeks after immunization but were also more insidious and evolved over a longer period of time. Of course, the large amounts of opioid medications she took likely masked some of the symptoms, at least initially.

(ECF No. 85, p. 3.)

Dr. Ehresmann suggests that petitioner's tetanus vaccination is one of "a number of stressors in her life over the past decade which themselves can be factors in amplifying chronic pain." (ECF No. 85, p. 3.) He explains that "[c]hronic pain syndromes that develop for a variety of reasons frequently do not have good clinical pathologic correlation." (*Id*.) He suggests that petitioner's post-vaccination pain is real even if it is not fully understood. He indicates that "[w]hether the pain is an exacerbation of pre-existing conditions, or a separate reactive process is difficult to ascertain." (*Id*.) He describes a number of more recent issues that have exacerbated her pain and note that "all of these factors influence the total pain experience for this patient, but do not refute the veracity of her post vaccination neuropathic and musculoskeletal pain syndrome." He suggests that "the neuropathic quality of her pain in her extremities has become more prominent, intrusive, and limiting in all of her daily activities" because she has come off of methadone. (*Id*. at 3-4.) Finally, Dr. Ehresmann notes that, although petitioner has stigmata of osteoarthritis, she does not have evidence of inflammatory arthritis at this time. (*Id*. at 4.) He has "recommended that she be seen in consultation by a neurologist with experience in post vaccination pain syndromes to assist in non-opioid pharmacologic management of her persistent symptoms which are more prominent now than in the weeks after her vaccination." (*Id*.)

IV. Finding of Fact

As explained in the procedural history above, I previously issued a finding of fact in this case. (ECF No. 42; *see also* 2021 WL 5764231 (Fed. Cl. Spec. Mstr. Sept. 29, 2021).) That finding of fact carefully evaluated Dr. Ehresmann's July 16, 2020 letter, along with the other evidence of record, to address the timing of onset and diagnosis for petitioner's alleged condition. That finding of fact remains operative, and it is not necessary to repeat that analysis. However, herein I briefly address why, applying the same legal standard as discussed in the finding of fact, the evidence subsequently filed by petitioner does not alter the conclusions reached within that finding of fact. I reached three conclusions within the finding of fact. I will address each in turn.

First, I concluded that "Dr. Ehresmann's letters lack the same indicia of credibility and reliability typical of contemporaneous medical records. Upon my review of the complete record, where Dr. Ehresmann's letter conflicts with petitioner's contemporaneous medical treatment records, petitioner's medical records should be given greater weight." (ECF No. 42, p. 21.) There were several factors that contributed to this conclusion, including the fact that Dr. Ehresmann had written numerous letters on petitioner's behalf that amounted to advocacy (which lacks the presumption of accuracy deriving from the context of medical treatment), that his various letters were inconsistent with one another, that the letters contained descriptions of petitioner's condition that conflicted with his own assessments included within his medical records, and that the July 16, 2020 letter in particular was not contemporaneous to the events at issue. (*Id*. at 15-21.)

I have now additionally considered Dr. Ehresmann's September 12, 2023 letter and do not find that it disturbs the analysis of my prior finding of fact. In fact, it reinforces my conclusion. The September 12, 2023 letter is even further removed from the events of 2015 than was the prior July 16, 2020 letter. Moreover, in now acknowledging that "[r]eactive arthritis is probably not the best descriptor" of petitioner's condition, he introduces further inconsistency into his stated view. (ECF No. 85, p. 2.) And, in any event, the letter remains consistent with his overall pattern of advocacy.

Second, I concluded that "the evidence preponderates only in favor of a finding that petitioner suffered a subjective increase in upper extremity joint pain following her Tdap vaccination no earlier than mid-November 2015 and no later than February 3, 2016. The record is inadequate to place onset of any other alleged symptom within that period." (ECF No. 42, p. 24.)

I have considered both Dr. Ehresmann's September 12, 2023 letter and the updated medical records from 2023. None of this evidence disturbs the analysis from the prior finding of fact. Although petitioner's 2023 medical records persistently report that she began experiencing symptoms "after" her tetanus vaccination, these reports are not very specific and occurred eight years after the fact. Special masters frequently give less weight to less contemporaneous medical histories. *See, e.g.*, *R.K. ex rel A.K. v. Sec'y of Health & Human Servs*., No. 03-0632V, 2015 WL 10936124, at *76 (Fed. Cl. Spec. Mstr. Sept. 28, 2015) (holding that more remote histories of illness do not have sufficient indicia of reliability to be credited over conflicting contemporaneous medical records and earlier reported histories), *mot. for rev. den'd*, 125 Fed Cl. 57 (2016), ***aff'd per curiam***, 671 Fed. App'x 792 (Fed. Cir. 2016); *see also, e.g.*, *Vergara v. Sec'y of Health & Human Servs.*, No. 08-882V, 2014 WL 2795491, *4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those *recounted in later medical histories*, affidavits, or trial testimony." (emphasis added)).

Importantly, the finding of fact addressed a body of medical records spanning into 2018, nearly three years post-vaccination. Thereafter, the subsequently filed medical records do not begin until 2023, nearly five years later. Moreover, Dr. Ehresmann's September 12, 2023 letter explains that petitioner's alleged post-vaccination symptoms "did begin in the weeks after immunization but were also more insidious and evolved over a longer period of time. Of course, the large amounts of opioid medications she took likely masked some of the symptoms, at least initially." (ECF No. 85, p. 3.) Though seeking to rationalize why petitioner's symptom presentation may still be compatible with a vaccine injury, this explanation by Dr. Ehresmann is actually compatible with, and therefore does not call into question, the prior finding of fact.

Third, I concluded that Dr. Ehresmann's July 16, 2020 letter was inadequate to support a diagnosis of reactive arthritis. (ECF No. 42, p. 25.) I explained that Dr. Ehresmann "focuses primarily on ruling out other possible explanations for petitioner's

symptoms and does not discuss what considerations are involved in diagnosing reactive arthritis." (*Id*.) I also noted that he

> asserts that a significant part of petitioner's post-vaccination presentation is the onset of neuropathic symptoms. However, despite highlighting neuropathic symptoms as an important part of petitioner's overall presentation, he has not identified them as contributing to any unifying diagnosis. Nor has he alternatively discussed why reactive polyarthritis would remain the best diagnosis if it does not encompass a substantial part of what he considers her relevant post-vaccination presentation.

(*Id*.)

I have considered both Dr. Ehresmann's September 12, 2023 letter and the updated medical records from 2023. None of this evidence disturbs the analysis from the prior finding of fact. In fact, in his letter Dr. Ehresmann specifically acknowledges that reactive arthritis is not a good diagnosis for petitioner. (ECF No. 85, p. 2.) Moreover, his more recent medical records from 2023 continue to not include reactive arthritis as an established diagnosis for petitioner, despite his prior letter to the court of July 2020 urging that she had suffered that condition. (ECF No. 85.) He continues to identify neuropathic symptoms as a significant part of petitioner's alleged post-vaccination presentation; however, neither his letter nor his 2023 treatment records identify any diagnosis to explain those symptoms. Instead, he recommends petitioner see a neurologist for such evaluation.

V. Analysis

a. Petitioner has not identified an injury

Petitioner "must specify [her] vaccine-related injury and shoulder the burden of proof on causation." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). "Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury – the Act specifically creates a claim for compensation for 'vaccine-related injury or death.'" *Stillwell v. Sec'y of Health & Human Servs.*, 118 Fed. Cl. 47, 56 (2014) (emphasis omitted) (quoting 42 U.S.C. § 300aa-11(c)). And, in any event, a petitioner must prove by a preponderance of the evidence the factual circumstances surrounding her claim. *See* 42 U.S.C. § 300aa-13(a)(1)(A). "[T]he function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)).

Here, petitioner alleged that she suffered reactive polyarthritis. However, she has not preponderantly established that she suffered that condition. As a threshold

issue, this diagnosis is not documented in any of petitioner's medical treatment records – not even those records by Dr. Ehresmann post-dating his July 2020 letter to the court urging that petitioner had suffered reactive arthritis. In any event, although Dr. Ehresmann had initially indicated he would support such a diagnosis, he later retracted that assertion, conceding that "[r]eactive arthritis is probably not the best descriptor" of petitioner's condition. (ECF No. 85, p. 2.) Dr. Ehresmann's opinion letters also include a broader assertion that petitioner's upper extremity pain was simply the first harbinger of an "insidious" onset of a broader constellation of symptoms, including musculoskeletal and neuropathic symptoms. (ECF No. 85; Ex. 8.) However, he has not come forward with any diagnosis that could serve as a basis for beginning to theorize how that presentation could have been vaccine-caused. This shortcoming is especially significant in this case, given petitioner's complicated overall medical history and chronic pain and disability attributable to other conditions.

Although I did find there is preponderant evidence that petitioner experienced an increase in upper extremity joint pain following her Tdap vaccination, beginning no earlier than mid-November 2015 and no later than February 3, 2016, petitioner has been entirely unable to explain this symptom. In order to present an "injury" cognizable under the Vaccine Act, "[m]edical recognition of the injury claimed is critical" and petitioner must assert "more than just a symptom or manifestation of an unknown injury." *Broekelschen*, 618 F.3d at 1349. Considering his written opinions collectively, Dr. Ehresmann has been inconsistent in identifying the nature of petitioner's upper extremity pain. (ECF No. 85; Ex. 8.) Even after abandoning reactive arthritis as any explanation, Dr. Ehresmann is still unclear with respect to whether petitioner's pain is neuropathic or musculoskeletal and has disclaimed any ability to further determine the nature or cause of the symptom. He has instead recommended she be evaluated by a neurologist. Apart from Dr. Ehresmann's opinion letters, petitioner has not provided any medical records or medical opinion evidence that could substantiate any other injury.

b. Petitioner has not established causation-in-fact

As explained above, cause-in-fact claims such as this are subject to the three-part *Althen* test. Here, the evidence petitioner has gathered is entirely inadequate to address *Althen* prongs one and three. Neither petitioner's medical records, nor Dr. Ehresmann's opinion letters, articulate any theory that could explain how petitioner's condition could be vaccine-caused. Without a theory, petitioner cannot demonstrate that the timing of onset of her alleged condition allows for an inference of causation. Additionally, even if she had established the theoretical possibility of a vaccine-related injury, there is not preponderant evidence of a logical sequence of cause-and-effect implicating petitioner's vaccination as an actual cause of the upper extremity pain she experienced post-vaccination.

In establishing that a vaccine "did cause" injury under *Althen* prong two, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1375; *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1280) (stating that "medical

records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'"). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* 42 U.S.C. § 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 745 n.67 (2009) (stating that "there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). A treating physician's opinion is only creditable if it has a sound medical basis. *See, e.g.*, *Garner v. Sec'y of Health & Human Servs*., No. 15-063V, 2017 WL 1713184, at *11 (Fed. Cl. Spec. Mstr. Mar. 24, 2017) (explaining that "the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals."), *mot. rev. denied,* 133 Fed. Cl. 140 (2017).

I have accepted that petitioner experienced upper extremity pain sometime between mid-November of 2015 and early February of 2016. However, although some of petitioner's medical records through 2018 belatedly acknowledged that she reported pain arising post-vaccination, none of those records, including those by Dr. Ehresmann, included any medical opinion agreeing that the reported symptom was vaccine-caused. (ECF No. 85, pp. 8-33.) It is notable that Dr. Ehresmann has a longstanding relationship with petitioner as her treating rheumatologist both before and after the vaccination at issue. He was therefore well positioned to detect petitioner's alleged vaccine injury, especially if it was a rheumatic injury such as reactive arthritis. Accordingly, his opinion warrants consideration with respect to the onset of upper extremity pain that is preponderantly established by the contemporaneous records. However, as I observed in my prior finding of fact:

> The suggestion that petitioner used her recurring IVIG infusion appointments as an opportunity to voice complaints to Dr. Ehresmann is understandable. The idea that Dr. Ehresmann would receive these complaints as diagnostic of a significant new condition without acting accordingly is far less understandable. Instead, Dr. Ehresmann's conduct as reflected by his treatment records is entirely in keeping with an understanding that petitioner's ongoing course of symptoms remained consistent with the chronic conditions which he was already treating rather than any new onset of a separate reactive polyarthritis. Petitioner's contemporaneous medical records consistently list several medical conditions that petitioner dealt with for years before and after her vaccination including, *inter alia*, Bechet's, goiter, hip trauma, ganglion cysts, osteoarthritis, anemia, hypothyroidism, and joint pain. (*Compare* Ex. 9, pp. 31106-08, 30691, 29311, 32729, 35219, 35781-82 (post-vaccination) and

> Ex. 9, pp. 13789-92, 15113-15, 21747, 21749-52, 21752-55, 24111, 24546-47, 24555-56 (pre-vaccination).) These conditions are consistently listed in assessments, medical histories, lists of active medical problems, symptoms, and exam findings. (*Id.*) Ultimately, based on the entirety of the record, it appears that Dr. Ehresmann never formally diagnosed petitioner with reactive polyarthritis, and instead, only mentioned it once in a letter drafted to assist petitioner in obtaining a motorized wheelchair, and once in a letter written to advance this claim. (*See* Ex. 9, pp. 27199-201; Ex. 8.)

(ECF No. 42, pp. 17-18.)

In his most recent letter, Dr. Ehresmann further explained that "[c]hronic pain syndromes that develop for a variety of reasons frequently do not have good clinical pathologic correlation." (ECF No. 85, p. 3.) He acknowledged that it would be "difficult to ascertain" whether any separate reactive process could be implicated. (*Id*.) Moreover, as noted above, he appears unable to distinguish whether petitioner's upper extremity pain is neuropathic or musculoskeletal. In fact, in discussing vaccine adverse events, Dr. Ehresmann discusses conditions such as Guillain Barre syndrome and complex regional pain syndrome – neither of which he opines petitioner suffered – rather than explaining how a reactive arthritis or any other rheumatic condition could result in symptoms such as he suggests petitioner experienced. Notably, to the extent he included neuropathic symptoms in his assessment, Dr. Ehresmann had acknowledged in his July 2020 letter that Behçet's disease can have neurologic sequelae. (Ex. 8, p. 4.) As initially discussed in the prior finding of fact, Dr. Ehresmann has also been inconsistent in asserting whether petitioner had any distinct onset of inflammatory arthritis post-vaccination. (ECF No. 42, p. 20.) Thus, Dr. Ehresmann has in effect ultimately conceded that he cannot explain the symptoms petitioner attributes to her vaccination.

Additionally, the record of the case does suggest (though it does not definitively demonstrate) a different explanation for the onset of petitioner's upper extremity pain that occurred during the period after her vaccination. As explained in the prior finding of fact, although petitioner was not reliable in asserting she had been "nearly completely off" of her prior narcotic pain medication prior to vaccination, she did acknowledge in her affidavit that one of her other physicians believed at the time that her upper extremity pain was due to weaning off of narcotic medication. (ECF No. 42, pp. 21-22 (discussing Ex. 1, p. 2).) In that regard, Dr. Ehresmann's April 2016 referral to Dr. Matthews likewise explained that petitioner was tapering her opioid medication. (Ex. 9, pp. 27198-98.) In his most recent letter, Dr. Ehresmann now agrees that petitioner's alleged post-vaccination symptoms "did begin in the weeks after immunization but were also more insidious and evolved over a longer period of time. Of course, the large amounts of opioid medications she took likely masked some of the symptoms, at least initially." (ECF No. 85, p. 3.) Further to this, he explained that more recently petitioner's neuropathic symptoms have "become more prominent, intrusive, and limiting" in response to her discontinuance of methadone. (*Id*.) Dr. Ehresmann's observations, especially when combined with his overall view that petitioner's pain complaints are

difficult to parse from her chronic presentation, is consistent with the possibility that petitioner's subjective pain complaints occurring in the weeks and months post-vaccination were consistent with fluctuations in her chronic course due to changes in her pain medication. Notably, in his contemporaneous February 2016 letter to Gallant Medical Supply, Dr. Ehresmann did characterize petitioner's new upper extremity pain complaints as an exacerbation of her chronic conditions, albeit while also referencing reactive arthritis. (Ex. 9, pp. 27199-201.)

Despite all of the above, Dr. Ehresmann is clear in both his September 2023 letter and his 2023 medical records in maintaining the view that petitioner suffered a vaccine injury of some kind. (ECF No. 85.) However, in the absence of any ability to explain petitioner's upper extremity pain, his opinion is necessarily limited to recognizing that the symptom arose post-vaccination. The Federal Circuit has explained that, "[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278 (citing *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992)). Thus, "[a] treating physician's recognition of a temporal relationship does not advance the analysis of causation." *Isaac v. Sec'y of Health and Human Servs*., No. 08-601V, 2012 WL 3609993, at *26 (Fed. Cl. Spec. Mstr. July 30, 2012).

VI. Conclusion

For the reasons discussed above, petitioner has failed to establish by preponderant evidence that she suffered any injury that was caused-in-fact by her vaccination. Although I did find that there is preponderant evidence that petitioner experienced subjective complaints of upper extremity pain sometime between about three weeks to three months post-vaccination, petitioner has not been able to identify any medically recognized condition that would explain this symptom. Nor, relatedly, has she come forward with a medical opinion that could support a logical sequence of cause and effect explaining how her vaccination did cause her upper extremity pain. Instead, her treating rheumatologist has explained that petitioner suffers a number of longstanding conditions that have resulted in an overall chronic pain syndrome from which it is difficult to parse any separate post-vaccination injury. Fluctuations in petitioner's pain presentation may have instead been explained by adjustments to her narcotic pain medication. But in any event, even setting other possible explanations aside, attribution of that symptom to vaccination on this record would amount merely to *post hoc ergo propter hoc* reasoning.

I stress that nothing in this decision is intended to minimize what petitioner has experienced. As Dr. Ehresmann explains, petitioner suffers several seriously painful conditions that have disabled her. For that, she has my sympathy. Nor does anything in this decision question petitioner's good faith in perceiving at least some of her pain as vaccine related. However, for all the reasons discussed above, I cannot conclude that

her vaccination more likely than not caused any distinct injury or otherwise played any role in the development of any of her conditions.

Accordingly, this case is now **DISMISSED**. The clerk of the court is directed to enter judgment in accordance with this decision.[10]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[10] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.